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Indian Standard

GUIDE FOR TESTING AND CALIBRATION OF ULTRASONIC THERAPEUTIC EQUIPMENT

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INDIAN STANDARDS INSTITUTION
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Indian Standard
GUIDE FOR TESTING AND CALIBRATION OF ULTRASONIC THERAPEUTIC EQUIPMENT

Acoustics Sectional Committee, LTDC 5

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Indian Standard
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0. FOREWORD

0.1 This Indian Standard was adopted by the Indian Standards Institution on 26 May 1986, after the draft finalized by the Acoustics Sectional Committee had been approved by the Electronics and Telecommunication Division Council.

0.2 This standard covers the testing and calibration of ultrasonic therapeutic equipment. The technique of measurements is given in Appendix A.

0.3 While preparing this standard, assistance has been derived from IEC Pub 150-1963 'Testing and calibration of ultrasonic therapeutic equipment', issued by the International Electrotechnical Commission (IEC).

0.4 In reporting the result of a test made in accordance with this standard, if the final value, observed or calculated, is to be rounded off, it shall be done in accordance with IS : 2-1960*.

1. SCOPE

1.1 This standard applies to apparatus designed for therapeutic use. Such apparatus consists of a generator of high-frequency electrical energy and a transducer, usually a disk of piezoelectric material, for converting this to ultrasound. The transducer is housed in a holder designed for local radiation of the ultrasound to the human body. The transducer and associated parts with their housing are known as the treatment head.

1.2 This standard provides suitable methods for calibrating the intensity of the ultrasonic beam produced by this apparatus and should enable both the manufacturers and the supervising agencies to provide proper labelling as set forth herein.

1.3 This standard relates only to ultrasonic therapeutic equipment employing plane circular transducers in accordance with present practice. If future developments should lead to other acceptable transducers, appropriate provisions will be added to these recommendations.

*Rules for rounding off numerical values (*revised*).

1.4 This standard relates only to physical characteristics of the apparatus. Therapeutic value and methods of use are not considered.

2. TERMINOLOGY

2.1 For the purpose of this standard, the terms and definitions given in IS : 1885 (Part 3/Sec 4)-1966* shall apply.

3. ACOUSTIC CHARACTERISTICS

3.1 The ultrasonic output waves produced may be unmodulated or modulated. Modulation may be sinusoidal, pulsed or that resulting from full or half wave rectification. When the modulation is less than 25 percent, the wave will be considered unmodulated.

NOTE — The degree of modulation is the quotient of the difference and the sum of the maximum and minimum pressure amplitudes of the wave.

3.2 The effective acoustic power output of a treatment head is the time average of the acoustic power, radiated by the treatment head in the forward direction into an approximately free field in water, under standard conditions (*see* **6**). It is expressed in watts.

3.3 The effective radiating area of a treatment head is 1·11 times the area measured at the treatment head face and using a particular circular baffle chosen to transmit 90 percent of the effective acoustic power as described in **6.3**.

3.4 The effective intensity of ultrasound radiated from a treatment head is the quotient of the effective acoustic power output and the effective radiating area. It is expressed in watts per square centimetre (W/cm^2).

3.5 The maximum intensity of a treatment head is, by convention $4/\pi$ times the time average of acoustic power (at maximum setting of output controls) measured near the centre of the treatment head face and using a circular baffle, of 1 cm diameter.

4. SAFETY AND CONTROL FEATURES

4.1 A meter indicating effective acoustic power output (as defined in **3.2**), or effective intensity (as defined in **3.4**), or both, shall be provided on the generator in the form of a meter or calibrated output control device.

4.2 Ultrasonic therapeutic equipment shall conform to the appropriate standards for safety of operation.

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*Electrotechnical vocabulary : Part 3 Acoustics, Section 4 Sonics, ultrasonics and under water acoustics.

5. TOLERANCES

5.1 The output meter or control device specified in **4.1** shall indicate the effective acoustic power, or the effective acoustic intensity, or both, with an accuracy of ± 15% when the output is greater than 50% of the maximum, and ± 20% when the output is between 10% and 50% of the maximum.

5.2 During five hours of continuous operation at maximum output and at rated supply line voltage, in water at 30 ± 3°C, the acoustic output shall remain constant within ± 15% of its initial value. If the apparatus is provided with a power indicating meter, this variation may increase from ± 15 to ± 20% after the first 30 minutes of operation.

5.3 The acoustic power shall not vary by more than ± 10% for variations of supply line voltage of ± 5%. No manual readjustment of the apparatus for compliance with this requirement is permitted.

5.4 The actual frequency shall not differ by more than ± 5% from the nominal frequency.

5.5 Tests for compliance with **5.1**, **5.2** and **5.3** shall be conducted after the treatment head has been immersed in tap water to a depth of 50 cm for a period of 48 hours.

5.6 The temperature of the treatment head face shall not exceed 45°C during 10 minutes radiation (at maximum setting of the output controls) in transformer oil having an initial temperature of 30°C. The volume of oil shall be at least two litres and it shall not be agitated or stirred by external means. The temperature may be measured with a small thermocouple attached in the centre of the treatment head face.

5.7 The effective radiating area shall be kept within ± 10% of the rated value.

5.8 The maximum intensity shall be kept within ± 10% of the rated value. The centre of the 1 cm diameter baffle at which the actual maximum intensity is found, shall lie within 1 cm of the centre of the treatment head.

5.9 The quotient of the maximum and the effective intensity shall not exceed two.

6. CALIBRATION PROCEDURES

6.1 All measurements shall be made with the treatment head operating into an approximately free field in water under standard conditions, that is degassed at 30 ± 3°C and under conditions such that no cavitation occurs.

6.2 The effective acoustic power output of a plane treatment head is preferably determined by the radiation pressure method.

6.3 The effective radiating area of a plane treatment head, as defined in **3.3**, shall be determined by the use of circular baffles and by measurements of the effective acoustic power output. That baffle is found (by interpolation, if necessary) which transmits 90% of the power measured without any baffle. This baffle area is then multiplied by 1·11 to obtain the effective radiating area.

6.3.1 The baffles shall consist of rings whose inner and outer surfaces are conical as shown in Fig. 1. The constituent material and design shall be such as to provide a degree of acoustic insulation ensuring that the sound intensity transmitted through the baffle wall does not exceed 3% of the incident intensity. The baffle is bounded at the end which faces the treatment head by the circular intersection of the inner and outer cone and the diameter of this circle determines the baffle area. The other end of the baffle (the base) shall have an outer diameter larger than the diameter of the radiating area of the treatment head to be tested. The baffles shall be centred on the face of the treatment head in such a way that the distance between the circular edge of each baffle and the face of the treatment head face $\leqslant \lambda$. A set of baffles shall be provided of diminishing diameters in steps of 5%, starting from the diameter of the face of the treatment head. The number of baffles required depends on the type of treatment head and should be sufficient to reduce the transmitted power to about 70% of that produced without baffle. In addition, a baffle of 1 cm diameter is needed to determine the maximum intensity.

7. LABELLING

7.1 Ultrasonic therapeutic equipment shall carry a nameplate, permanently attached, on which the following information shall be given:

a) Frequency of ultrasound in megahertz (megacycles per second);

b) Effective acoustic power output in watts at maximum setting of output controls;

c) Effective intensity in watts per square centimetre, at maximum setting of output controls; and

d) Wave form (continuous, modulated or pulsed).

7.1.1 The maximum intensity shall be indicated in the accompanying papers.

7.1.2 If modulated or pulsed, the output waveform, duty factor and repetition rate shall be indicated in descriptive literature accompanying the equipment.

7.2 The effective radiating area of the treatment head (in square centimetre) shall be marked on its housing.

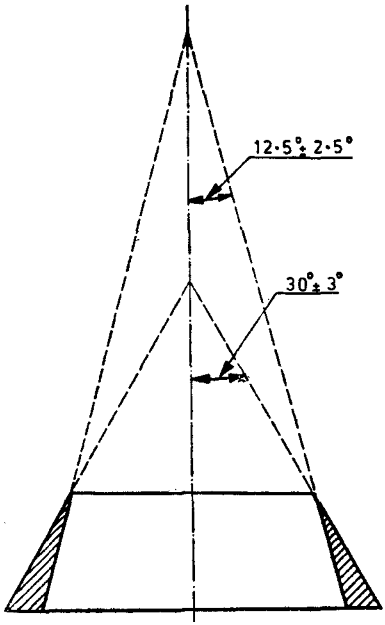

FIG. 1 CIRCULAR BAFFLE (CROSS-SECTION THROUGH A DIAMETER)

APPENDIX A

(*Clause* 0.2)

TECHNIQUE OF MEASUREMENTS

A-1. Approximate free field conditions may be obtained by use of suitable baffles, lining materials (for example, rubberized horsehair upholstery batting), size and shape of tank, etc.

A-2. Degassing of water shall be accomplished by boiling for 15 minutes at atmospheric pressure or by subjecting to a reduced pressure of not more than 30 mm of mercury for 3 hours. Degassing shall be carried out at least once within the 12 hours' period preceding each set of measurements unless special storage methods are used. In any case, care shall be taken throughout all procedures to minimize re-solution of air in water.

A-3. Cavitation may be avoided by degassing the water and by keeping the ultrasound intensity below that which produces cavitation. This latter

procedure may occasionally require an extrapolation in calculating maximum output characteristics. It is then necessary to assume that extrapolation is justifiable.

A-4. Radiation pressure measurements shall be made using a sensitive element which has a light-weight reflecting interface (namely, thin metal foil backed by air) so arranged as to avoid standing waves. A cone or prism of 45° half-angle is convenient. The reflector shall be large enough to intercept the entire beam and its nearest point shall be placed between one and three transducer diameters from the treatment head face.

A-5. It is preferable either to use compensating radiation meters, that is, radiation meters with which the measurements are made not on the basis of displacement of a sensitive part but of the force required to return it to the initial state, or to use devices in which the sensitive part is displaced in a direction parallel to itself and remains at a constant angle with respect to the direction of ultrasonic emission. For example, a torsional spring or a float may be used. Damping of the measuring system must be sufficient to integrate the modulations of the radiation. The calibration shall be by means of standard weights. The effective acoustic power output, in watts, is

$$W = \frac{F \cdot c}{2 \cos^2 A}$$

where

F = force exerted by the sound beam on the reflector along the beam axis,

c = velocity of sound in water, and

A = angle between the normal to the reflecting surface and the beam axis.

The units for power, force and velocity are : watts, newtons and metres per second in the MKSA system and ergs per second, dynes and centimetres per second in the CGS system.

The numerical value of c at 30°C may be taken as 1 510 m/s or 151 000 cm/s.

When the reflection coefficient of the reflecting interface differs significantly from unity, the factor 2 in the denominator in the formula must be replaced by (1 + r) where r is the intensity reflection coefficient. If the force F is measured normal to the reflector, the denominator contains $\cos A$ instead of $\cos^2 A$.

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